SUBJECT: Electronic Loading of Laboratory Data under the caBIG™ Program	SOP No.: IT-003
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Standard Operating Procedure – Electronic Loading of Laboratory Data

This cover sheet controls the layout and components of the entire document.

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for the loading of laboratory data into a clinical data management application.

2. Scope

This SOP will be used for the loading of all electronic laboratory data for clinical trials research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI) .

3. Requirements

3.1 Laboratory data must exist electronically and the format of the content must be fixed and pre-defined with NCICB. It is essential that all variables that must be included in any data transfer, regardless of where the data originated from or the information contained within.

3.2 Procedures must be in place detailing the collection, transfer, loading, validating and editing of external data through internal (NCI intra/extra mural sites) and vendor collaboration.

3.3 A documentation trail must be maintained for data loaded electronically into NCICB clinical data management system.

3.4 Written procedures must be in place to safeguard the statistical blind when primary efficacy data are collected externally and loaded into NCICB clinical data management systems.

3.5 Quality control procedures should be applied at every stage of the data handling process to ensure that all data are reliable and have been processed correctly.

3.6 External data should be monitored on a regular basis for consistent format and content.

3.7 A formal process should be in place to handle the deletion or back-out of electronic data loaded incorrectly.

3.8 In all cases, complete naming conventions and labeling information must be established to facilitate the transmission process and to help address any issues that may arise as a result of electronic data being lost or loaded incorrectly.

3.9 Timelines for all data transfer and loading will be established in advance between NCICB and vendors supplying electronic data for loading.

3.10 All staff responsible for assuming the roles identified in the Roles and Responsibility section will receive training on this SOP.

4. References/Regulations/Guidelines

Section	Document Number	Title
4.1	N/A	CDISC Glossary
4.2	CR004	SOP for CDE Curation
4.2	N/A	CDE Loader Utility Usage Guide
4.3	N/A	HL7 Working Group. *An Application Protocol for Electronic Data Exchange in Healthcare Environments.* Health Level Seven, Inc.
4.4	N/A	Association for Clinical Data Management (ACDM). *Standards for Electronic Transfer of Laboratory Data.*

5. Roles & Responsibilities

Role	Responsibility
Lab Loader Technician	• External Loads – inspect file, load staging tables, process file. • Problem analysis and resolution for automatic loading.
Help Desk Technician	• Problem analysis and resolution for automatic loading. • Refer significant problems to appropriate Loader Technician.
Study Coordinator	• Verify correct data is loaded. • Contact Help Desk with any errors or issues.
NCICB Project Director	• Authorize any deletion of data as “Soft” (audit trail will record transaction) or “Hard” (all traces of record will be removed).

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Loading Electronic Laboratory Data: http://cabigcvs.nci.nih.gov/viewcvs/viewcvs.cgi/ctms_best_practices/SOP_Working_Group/Issued_SOPs/IT003_PD_Automatic_Lab_Loading.pdf	This document provides instructions for loading electronic laboratory data. This procedure also includes load back-out procedures, re-loads and management and resolution of partial load results.
2) Process Flow for Loading Electronic Lab Data: http://cabigcvs.nci.nih.gov/viewcvs/viewcvs.cgi/ctms_best_practices/SOP_Working_Group/Issued_SOPs/IT003_WF_Electronic Loading_of_Lab_Data.pdf	This document visually depicts the activities, by role, for electronically loading laboratory data.